California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Enforcement Committee Report

John Jones, Chair
Stan Goldenberg
Don Gubbins, Jr.
Bill Powers

Report of July 2, 2003

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy amend California Code of Regulation section 1711 to clarify the pharmacist's responsibility when notifying the patient and prescriber of a prescription error.

Discussion
Proposed modifications were submitted to clarify the pharmacist's responsibility when notifying the patient and prescriber of a prescription error. Working with the stakeholders, proposed language was drafted to allow for the pharmacist's professional judgment when situations do not require immediate notification or when the patient has not taken the wrong medication. **(Attachment A)**

RECOMMENDATION 2

That the Board of Pharmacy interpret Business and Professions Code section 4059.5 to allow the delivery of prescription drugs to a secured area when a pharmacy is closed and to seek a statutory change consistent with this interpretation.

Discussion
It was requested that the board consider its interpretation of Business and Professions Code section 4059.5 to allow for the delivery of prescription drugs to a secured area when a pharmacy is closed. The law requires that the dangerous drugs must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge.

It was presented that due to various local ordinances and environmental factors, delivery of prescription drugs must take place after the pharmacy is closed. It was requested that the board consider the delivery of the prescription drugs to a secured area as the

prescription drugs still being in transit. It is when the pharmacy takes possession of the drugs that the drugs would be considered delivered to the pharmacy in compliance with 4059.5. The wholesaler would be responsible until such time that the pharmacy took possession.

The committee is recommending that the board interpret the statute that would allow for the delivery to a secured area. However, once the drugs were delivered to the secured area, the drugs would no longer be in transit and the pharmacy would be responsible for the prescription drugs. **(Attachment B)**

RECOMMENDATION 3

That the Board of Pharmacy delegate to the executive officer as part of the licensing process the authority to approve requests submitted pursuant to Health and Safety Code section 11164.5.

Dr. Cacciatore of CardinalHeath presented a proposal to license a pharmacy service center in California. This would be an office-based, licensed pharmacy staff with experienced hospital pharmacists. The hospital would transmit new orders to the service center after the hospital pharmacy closes or when needed via fax or digital imaging. Pharmacists at the pharmacy service center would remotely access the hospital computer system and review orders, perform prospective drug use review, and approve orders within 60 minutes. Pharmacists would also be available via a toll free number to answer medication questions from nursing and medical staff.

The pharmacy service center would have access to the hospital pharmacy computer system through a secure, virtual private network. The pharmacy service center would also enter into a Business Associate agreement with the hospital and would be in full compliance with HIPAA and state privacy laws.

It was noted that Business and Professions Code section 4071.1 allows for a pharmacist to electronically enter a prescription or order into a hospital's computer from any location outside the pharmacy or hospital with the permission of the pharmacy or hospital. Health and Safety Code section 11164.5 allows for electronic data transmission or computer entry of prescriptions for controlled substances if authorized by federal law and with the approval of the Board of Pharmacy and the Department of Justice.

Dr. Cacciatore stated that CardinalHealth will be submitting a community pharmacy application for licensure of this facility. He also stated that he will submit a written request for approval Health and Safety Code section 11164.5 to enter in the hospital computer system controlled substances. He will be submitting a request for approval to the Department of Justice and the Board of Pharmacy.

The committee agreed that the licensure of this facility as a community pharmacy was appropriate and directed staff to work with the Department of Justice regarding the

approval process as provided in the Health and Safety Code for controlled substances. The committee also agreed to recommend that the executive officer be delegated the authority as part of the licensing process to approve these requests. **(Attachment C)**

NO ACTION

Importation of Drugs from Canada

The board will continue its discussion regarding the importation of drugs from Canada. **(Attachment D)**

Report on the Task Force Meeting with the Medical Board of California on Prescriber Dispensing

The Medical Board of California and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the recordkeeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, recordkeeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

He stated that the task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004. **(Attachment E)**

Enforcement Committee Meeting Summary of July 2, 2003 (Attachment F)

Enforcement Team Meeting Summary of July 2, 2003 (Attachment G)

Report on Enforcement Actions (Attachment H)

Final Report on Committee Goals for 2002/2003 (Attachment I)

Attachment A

Draft Amendments to Section 1711
Quality Assurance
July 9, 2003

§1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
~~(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless the pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.~~
(c) (1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.
(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
(B) Communicate to the prescriber the fact that a medication error has occurred.
(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and,
4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.
(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.
(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.
~~(i) This section shall become operative on January 14, 2002.~~

CSHP | CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

725 30th Street, Suite 208 Sacramento, CA 95816
(916) 447-1033 Fax No. (916) 447-2396

July 1, 2003

Patricia Harris
Executive Officer
California Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814-6237

RE: Request for amendments to California Code of Regulations, Title 16, Division 17, Section 1711 (Quality Assurance Programs)

Dear Patty,

The purpose of this letter is to request, ***on behalf of the California Society of Health-System Pharmacists, the California Pharmacists Association Long Term Care Management Council, Albertson's and Kaiser Permanente*** that the Enforcement Committee consider this proposal to amend Section 1711 of the California Code of Regulations (Title 16, Division 17). (Full text of 1711 is attached).

At the April 2003 Board meeting, the stakeholders interested in this issue were asked to meet to agree on language. The aforementioned have done so, and propose the following amendment (changes are double underlined) to the language that the Enforcement Committee provided to the Board in April 2003. (A copy of the full text of the 1711, with the proposed changes included, is also attached.)

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless ~~the~~ **a** pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall ~~immediately~~ **as soon as possible, and working in collaboration with the prescriber or the prescriber's agent, ~~or if unavailable, another prescriber then treating the patient,~~** communicate to the patient **or the patient's representative or care provider** ~~and the prescriber~~ the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error. **The provisions of this subsection (c) shall only apply to medication errors in which the patient took, or was administered a drug in error.**

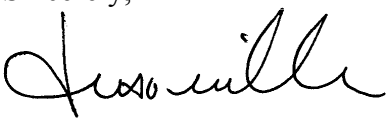
Rationale for Proposed Changes

1) Inclusion of the term "*prescriber's agent"* addresses the concern raised about different situations, including those likely to be encountered in, but not limited to, acute care, long term care and community practice settings.

2) We agree that **all** medication errors should be subjected to review for the purpose of identifying system errors that can be corrected in order to avoid future errors. However, we feel that notification of the patient and the prescriber in *every* instance is not necessary, nor is it the most prudent use of health care resources. Therefore, we have proposed language that would modify the requirement that the patient and prescriber be notified in every instance, to one in which they must be notified if the patient actually takes, or is administered, a medication in error.

Thank you for considering our request. Please feel free to contact me if you need additional information.

Sincerely,



Teresa Ann Miller, Pharm.D.
Executive Vice President, Chief Executive Officer
California Society of Health-System Pharmacists

cc: John Jones, Chair, Board of Pharmacy Enforcement Committee
Stan Goldenberg, Member, Board of Pharmacy Enforcement Committee
Paige Talley, CPhA Academy of Long Term Care Management Council
Rich Mazzoni, Director, Pharmacy Professional Services and Govt Relations, Albertsons,
Steve Gray, Director, Pharmacy Professional Affairs, Kaiser Permanente, CA Division
Carlo Michelotti, CEO, California Pharmacists Association
CSHP Board of Directors

PROPOSED AMENDMENTS TO

CALIFORNIA CODE OF REGULATIONS
TITLE 16, DIVISION 17
Section 1711

July 1, 2003

1711:

(a) Each pharmacy shall establish or participate in an established quality assurance program, which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless ~~the~~ **a** pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall ~~immediately~~ **as soon as possible, and working in collaboration with the prescriber or the prescriber's agent, ~~or if unavailable, another prescriber then treating the patient,~~** communicate to the patient **or the patient's representative or care provider** ~~and the prescriber~~ the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error. **The provisions of this subsection (c) shall only apply to medication errors in which the patient took, or was administered a drug in error.**

(c) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(d) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c)
3. the findings and determinations generated by the quality assurance review; and,
4. recommend changes to pharmacy policy, procedure, systems or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems or processes made as a result of recommendations generated in the quality assurance program. (f)

(e) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(f) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(g) Nothing in this section shall be constructed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

(i) This section shall become operative on January 14, 2002.

Attachment B

Board of Pharmacy
Draft Amendments for After-Hours Delivery

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.
(b) A dangerous drug or dangerous device transferred, sold, or delivered to any person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.
(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices.
(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. Any person or entity receiving delivery of any dangerous drugs or devices, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drugs or dangerous devices.
(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the drugs or devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the drugs or devices are to be delivered shall include, but not be limited to, determining that the recipient of the drugs or devices is authorized by law to receive the drugs or devices.
(f) Nowithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.
(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge shall have access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.
(3) The secure storage facility shall have a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.
(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.
(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision shall leave documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

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Albertsons

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By facsimile to (916) 327-6308 and U.S. Mail

January 17, 2003

California Board of Pharmacy
Attn: Patty Harris, Executive Officer
400 R Street, Suite 4070
Sacramento, CA 95814

Re: California's Proposed Wholesale Drug Transactions Regulations, Title 16, Sections 1784 and 1785

Dear Board Members:

This is in response to your request that Albertsons provide written comment on the proposed regulations pertaining to Wholesale Drug Transactions. We contend that section 1784, as currently proposed, would significantly impede legal trade and commerce in our industry and would directly and significantly hinder our ability to compete in the marketplace. While we understand and appreciate the core purpose of the proposed language and the desired result, we believe that its effect will go far beyond the Board's purpose and will negatively impact patient care in the areas of supply and cost.

We submit that adoption of the language proposed for section 1785 with one minor change (as indicated on the attached) is adequate to carry out the Board's purpose in that it provides a sufficient audit trail for enforcement purposes without the significant impact on trade and commerce. We propose that the Board modify section 1785, as indicated, to provide consistency with standard industry terminology, and that section 1784 be stricken in its entirety.

As always, we would be happy to answer questions or provide additional information or testimony, as necessary. We appreciate the Board's consideration.

Respectfully submitted,

ALBERTSON'S, INC.

Rich Mazzoni /lb

Rich Mazzoni, Director
Pharmacy Professional Services
and Government Relations

RM:lb
Enclosure
cc: David Vucurevich

Walgreens

May 9, 2003

Patricia F. Harris
Executive Officer
California State Board of Pharmacy
400 R. Street Suite 4070
Sacramento, CA 95814

Re: After Hours Receiving of Pharmaceuticals

Dear Ms. Harris:

Walgreens Co. seeks the approval from the Board to implement a new procedure for receiving pharmaceuticals outside the business hours of the pharmacy, in the absence of a pharmacist.

Each of our stores is equipped with a secure room that is located outside of the pharmacy department. This room is secured by two methods, a lock and a door seal that is marked with a serial number.

The delivery of pharmaceuticals after hours would be placed into this secure room. The delivery person and a member of Walgreens' management would secure the delivery, record the serial number of the door seal on a log sheet, along with the date and time received, and the number of parcels received. The following business day, the pharmacist would receive the delivery by checking that the unbroken seal on the door matches the serial number indicated on the log sheet and account for the proper number of parcels delivered. The pharmacist would be the only person with possession of the key to this secure room.

We believe that this proposed procedure would ensure safe delivery of pharmaceuticals to our pharmacies during the absence of a pharmacist. The majority of our deliveries are during business hours of the pharmacy and this policy would only be implemented in a small number of stores where deliveries are made outside the business hours of the pharmacy.

Thank you for your consideration. If there are any questions or comments on our proposal, please feel free to contact me.

Sincerely,

Philip P. Burgess, R.Ph.
National Director, Pharmacy Affairs
(847) 914-3241
Phil.Burgess@Walgreens.com

PPB/sr

(i) This section shall become operative on July 1, 2001.
(Amended Stats. 2001, Chapter 159)

4059.5. Who May Order Dangerous Drugs or Devices: Exceptions; Compliance With Laws of All Involved Jurisdictions

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to any person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(C) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. Any person or entity receiving delivery of any dangerous drugs or devices, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drugs or dangerous devices.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to any person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the drugs or devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the drugs or devices are to be delivered shall include, but not be limited to, determining that the recipient of the drugs or devices is authorized by law to receive the drugs or devices.
(Added Stats. 1997, Chapter 549)

4060. Controlled Substance - Prescription Required; Exceptions

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, or veterinarian, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a physician assistant pursuant to Section 3502.1. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, physician, podiatrist, dentist, veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.
(Amended Stats. 2001, Chapter 289)

4061. Distribution of Drug as Sample; Written Request Required

(a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, or veterinarian. However, a certified nurse -midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to a protocol described in Section 3502.1, may sign for the ***request and receipt of complimentary samples of a dangerous drug or dangerous device that has been ***identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725 or 3502.1, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, or physician assistant shall be defined within the standardized procedure, protocol, or practice agreement.

(b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, or physician assistant, if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

(c) Nothing in this section is intended to expand the scope of practice of a certified nurse-midwife, nurse practitioner, or physician assistant.
(Amended Stats. 2002, Chapter 263)

4062. Furnishing Dangerous Drugs During Emergency

Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name and address of the person to whom the drug or device is furnished, and the name, strength and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
(Amended Stats. 1997, Chapter 549)

4063. Refill of Prescription for Dangerous Drug or Device; Prescriber Authorization

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.
(Amended Stats. 1997, Chapter 549)

4064. Emergency Refill of Prescription Without Prescriber Authorization

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the

From NACDS – 7/1/03

CA Breg 1714.2 – After Hours Receiving of Dangerous Drugs and Devices

(a) Pursuant to Section 4059.5 of the Business and Professions Code, except as otherwise provided, dangerous drugs and devices may only be ordered, and must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge, or in his or her absence, another pharmacist designated by the pharmacist-in-charge.

(b) The delivery of dangerous drugs and devices to licensed premises, and receipt and signature of receipt by the pharmacist-in-charge or his pharmacist designee, must occur contemporaneously unless the pharmacy licensee or the pharmacist-in-charge maintains a written policy and procedure for the secure delivery and storage of dangerous drugs and devices that are awaiting receipt and signature of receipt by the pharmacist-in-charge or his pharmacist designee. Such policy and procedure shall be applicable only to deliveries made during periods when the pharmacy is closed and no pharmacist is on duty.

(c) The written policy and procedure described under subsection (b) shall be submitted to the board for approval. It shall be deemed to be approved by the board if the board has not notified the licensee or pharmacist-in-charge otherwise within 30 days of submission to the board. The written policy and procedure shall be available to board inspectors during routine inspections.

Attachment C

CardinalHealth

Off-Site Order Entry of Hospital Medication Orders

Gary Cacciatore, Pharm.D., J.D.
Director of Regulatory Affairs

May 8, 2003

Background

- Focus on medication safety
  - Institute of Medicine "To Err is Human" report demonstrates medication errors lead to 7,000 deaths/year
    - Lazarou J, JAMA 1998;279:1200-5.
  - "Better patient monitoring and review of orders before the drug was administered to the patient were major mechanisms for preventing fatal ADEs."
    - Kelly WN, Am J Health Syst Pharm. 2001;58:1317-24

CardinalHealth

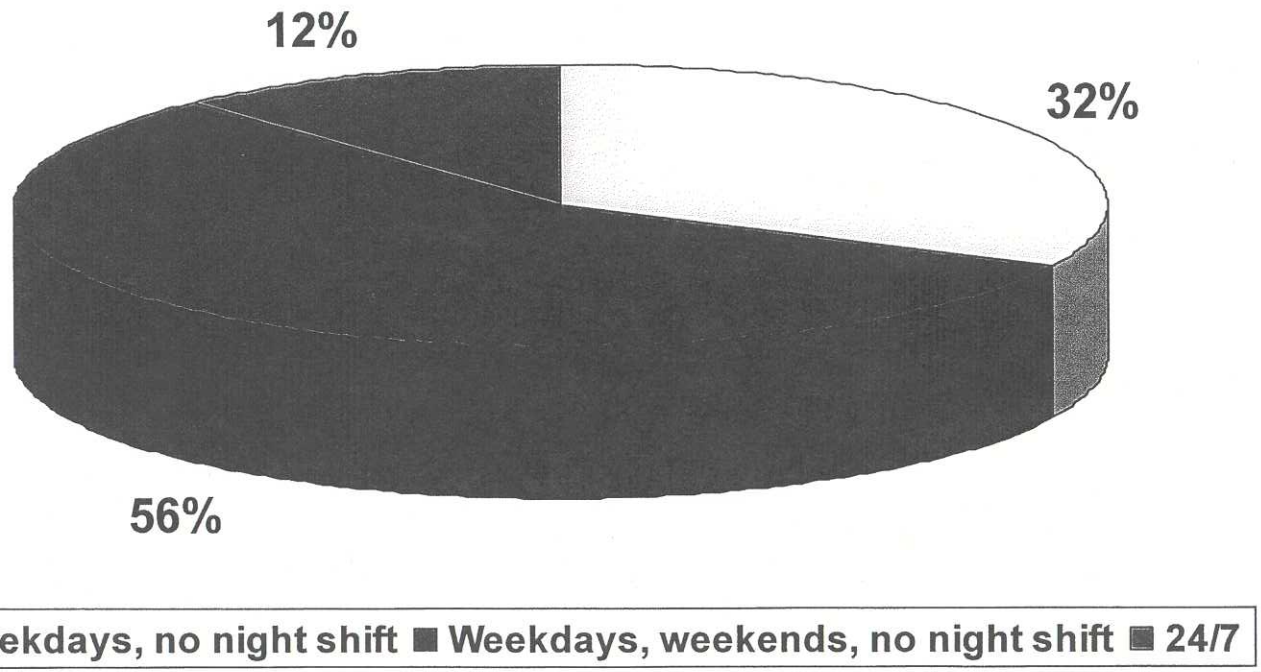
Background

- Accreditation /Regulatory Standards
  - JCAHO standards
    - TX 3.5.2 Pharmacists review each prescription or order for medication and contact the prescriber or orderer when questions arise.
    - TX 3.5.4 Pharmacy services are available when the pharmacy department is closed or not available.
  - Regulatory Standards
    - Many state boards have regulations regarding review of orders by pharmacist prior to dispensing
  - CMS (Centers for Medicare & Medicaid Services)
    - Consistent level of care

CardinalHealth

Background

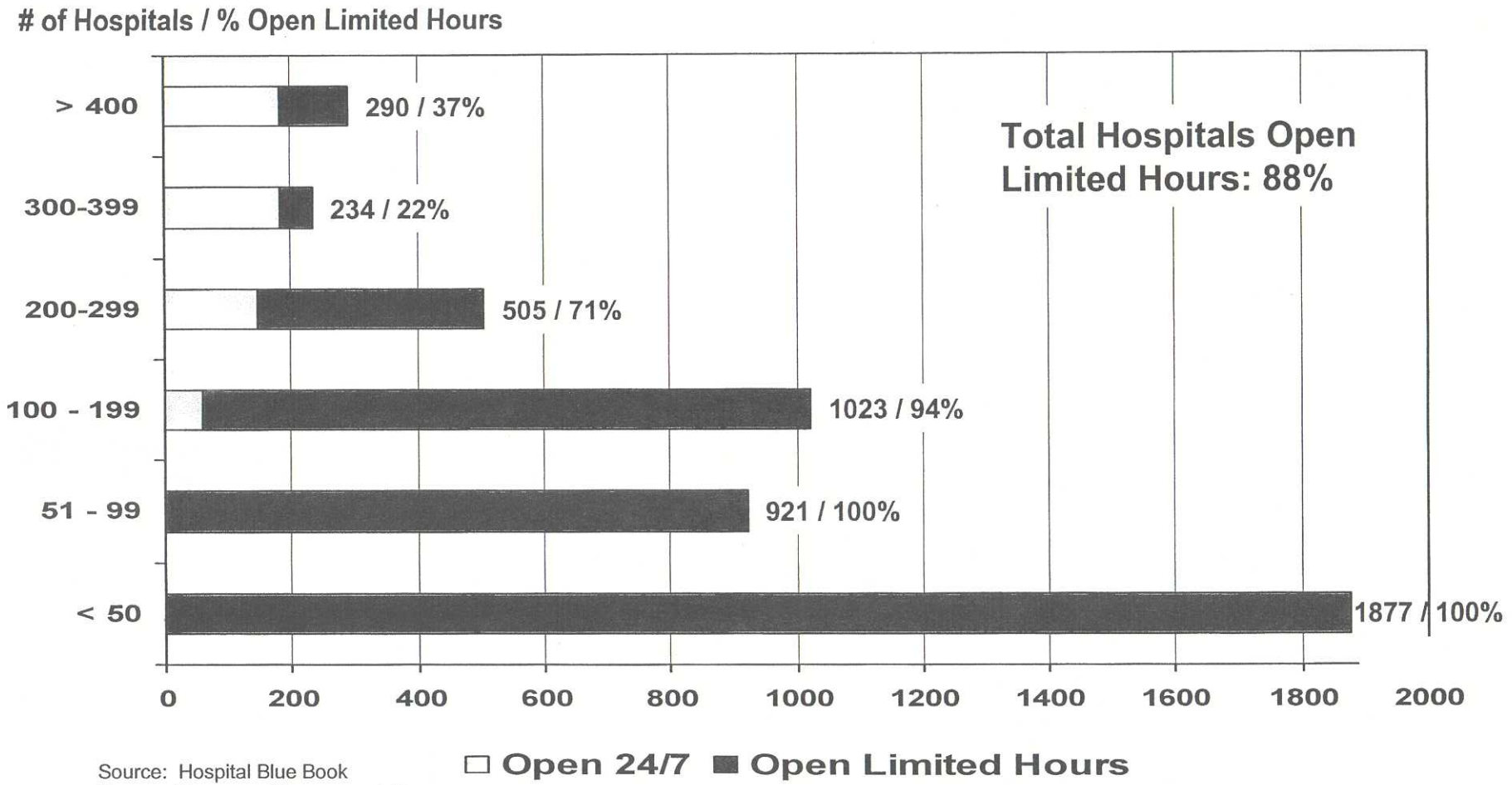
Only 12% of hospitals have 24/7 pharmacy services
88% of hospitals have at least some gap in coverage



Source: Pharmacy Management Survey

CardinalHealth

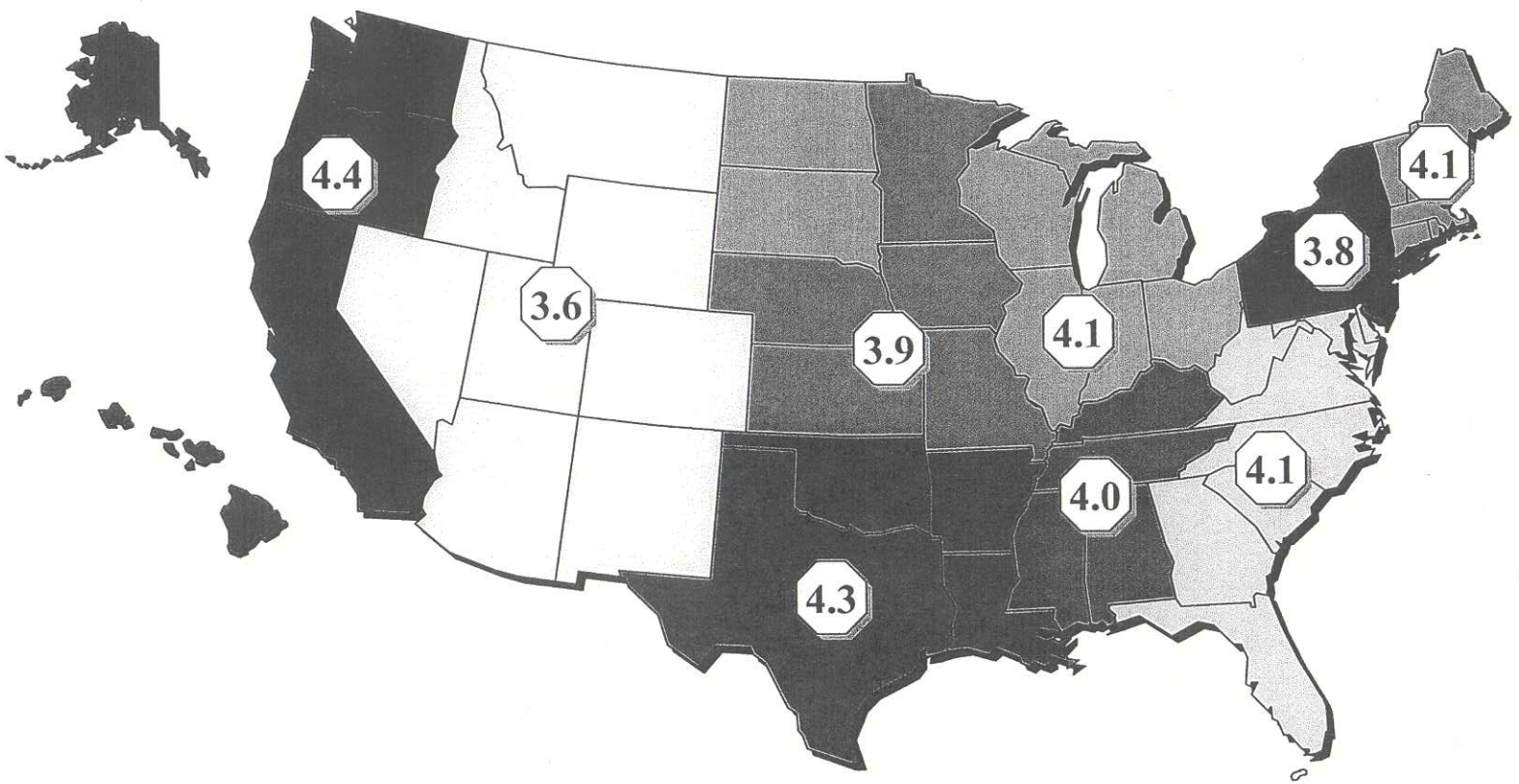
Background



Source: Hospital Blue Book
Source: Pharmacy Management Survey

CardinalHealth

Pharmacist Demand Index



1= Pharmacist Supply Adequate

5 = Severe Pharmacist Shortage

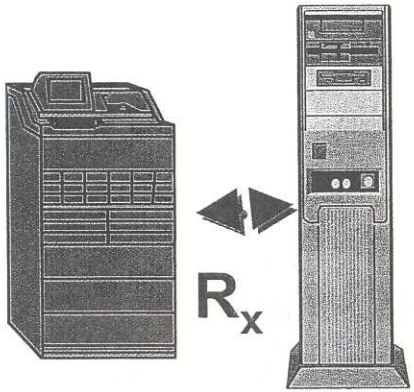
CardinalHealth

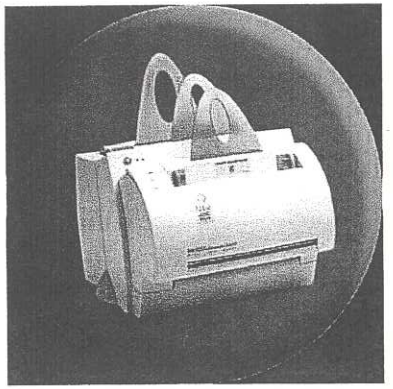
R_xe-source℠

- Pharmacy Service Center, an office-based, licensed pharmacy staffed with experienced hospital pharmacists established by Cardinal Health.
- Hospitals transmit new orders to the Pharmacy Service Center after the hospital pharmacy closes or when needed via fax or digital imaging system.
- Pharmacists at the Pharmacy Service Center remotely access the hospital pharmacy computer system and review orders, perform prospective drug use review, and approve orders within 60 minutes.
- Pharmacists are also available via toll free number to answer medication questions from nursing and medical staff.

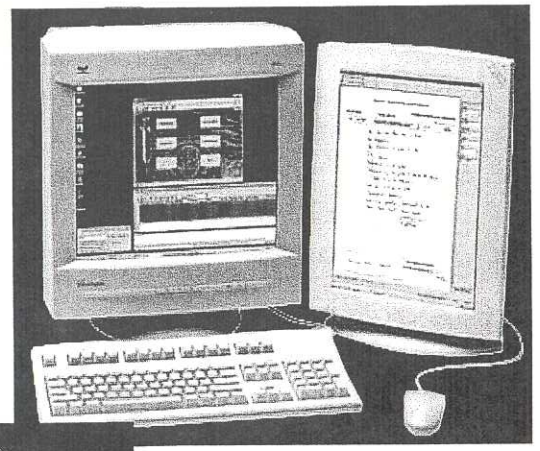
CardinalHealth

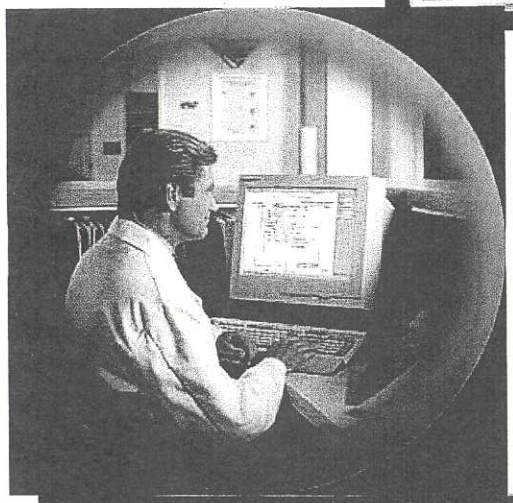
Hospital





Pyxis Connect, Fax, or Scan





Pharmacy Service Center

CardinalHealth

R_xe-*source*SM

- Training
  - Pharmacists are trained on each hospital's policies, procedures, and protocols prior to initiation of the service.
  - Copies of hospital pharmacy's policies and procedures are kept on site at the Pharmacy Service Center.
  - Pharmacy Service Center is staffed with pharmacists experienced in hospital pharmacy.
- Recordkeeping
  - System is able to identify each individual who processes an order.

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R_xe-source℠

- Measurements and Reports
  - Pharmacy Service Center staff document all interventions such as interaction avoidance, illegible order clarification, incomplete order clarifications, dosing changes, therapy duration changes, drug information provided, adverse drug reaction reporting, therapeutic interchange, etc.
- Confidentiality and Security
  - Remote access to hospital pharmacy computer system is through a secure, virtual private network.
  - Pharmacy Service Center enters into a Business Associate agreement with hospital and is in full compliance with HIPAA and state privacy laws.

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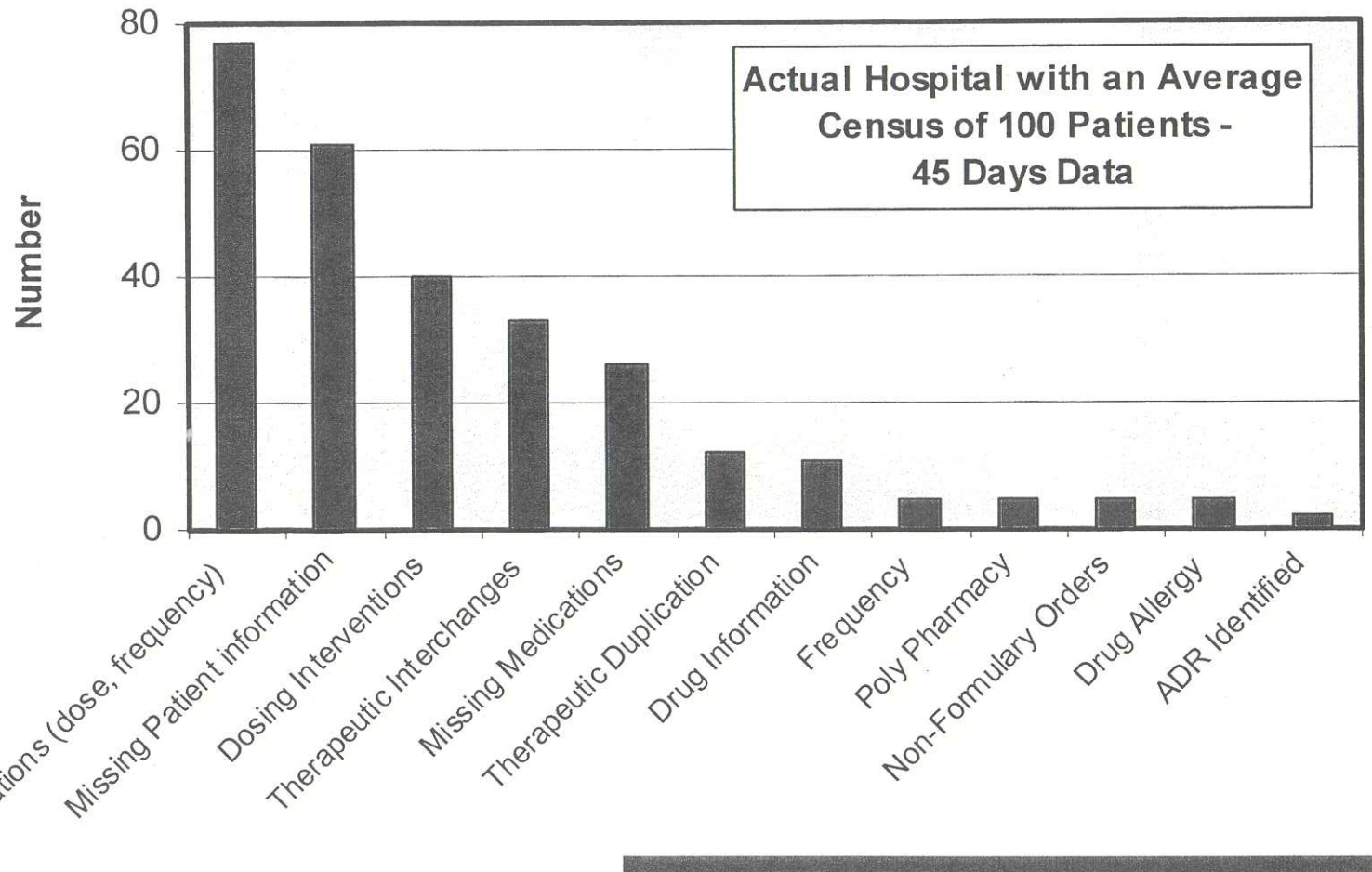
Service Benefits

- Patients
  - Improved continuity of patient care
  - Avoidance of adverse medication events
- Pharmacist
  - Ease staffing pressures
  - Focus on professional patient care functions
- Nurses
  - Safety of order authorization
  - Drug Information Resource

CardinalHealth

Texas Pharmacy Service Center



CardinalHealth

California Law

- Business and Professions Code 4071.1
  - "A prescriber, a prescriber's agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital....This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health & Safety Code."

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California Law (cont'd)

- Health and Safety Code 11164.5
  - "Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision."

Next Steps

- Location of Pharmacy Service Center already identified.
- Application for pharmacy license.
- Request for approval to include controlled substances.

CardinalHealth

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

MAY 23 2003

Mr. Gary Cacciatore
Director of Regulatory Affairs
Cardinal Health
1330 Enclave Parkway
Houston, Texas 77077

Dear Mr. Cacciatore:

This is in response to your correspondence dated May 16, 2003, requesting the Drug Enforcement Administration (DEA) to review Cardinal Health's Rx-E-Source system for compliance with our regulations. Rx-E-Source is an Internet based remote order entry system utilized by hospitals for in-patient medication orders. Personnel at hospital locations enter orders for in-patients into the system and pharmacists at Cardinal Health's support center, located at a separate location, will review the orders prior to the medications being administered to the hospital patients. Rx-E-Source provides pharmacist services to hospitals that may not have on-site pharmacist coverage available 24 hours a day, seven days a week.

The DEA has no regulatory authority over entities that do not possess or handle controlled substances. Under the circumstances described above, the pharmacists at Cardinal Health's support center do not have access to controlled substances and the centers do not stock controlled substances. The only activity taking place at the support center is pharmacists performing drug utilization reviews of medication orders for patients that are located in hospitals. The hospitals where the controlled substances are actually being administered to the patients must remain registered with the DEA and comply with federal controlled substance laws and regulations.

I trust this information addresses your concerns. The DEA appreciates the opportunity to assist registrants in their efforts to comply with our controlled substance regulations. If you have additional questions, please contact Vickie B. Seeger, R.Ph. at (202) 307-7297.

Sincerely,

Robert C. Williamson

for Patricia M. Good, Chief
Liaison and Policy Section
Office of Diversion Control

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

(Added Stats. 2000, Chapter 681)

Article 4. Requirements for Prescriptions

4070. Reduction of Oral or Electronic Prescription to Writing

(a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of Section 4040 shall as soon as practicable be reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy.

(b) A pharmacy receiving an electronic transmission prescription shall not be required to reduce that prescription to writing or to hard copy form if, for three years from the last date of furnishing pursuant to that prescription or order, the pharmacy is able, upon request by the board, to immediately produce a hard copy report that includes for each date of dispensing of a dangerous drug or dangerous device pursuant to that prescription or order: (1) all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040, and (2) the name or identifier of the pharmacist who dispensed the dangerous drug or dangerous device. This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(c) If only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's computer system shall not permit the received information or the dangerous drug or dangerous device dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law once the information has been received by the pharmacy and once the dangerous drug or dangerous device has been dispensed. Once a dangerous drug or dangerous device has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall impair the requirement to have an electronically transmitted prescription transmitted only to the pharmacy of the patient's choice or to have a written prescription. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

(Amended Stats. 2000, Chapter 293)

4071. Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded

Notwithstanding any other provision of law, a prescriber may authorize his or her agent on his or her behalf to orally or electronically transmit a prescription to the furnisher. The furnisher shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent of the prescriber who transmits the order.

This section shall not apply to orders for Schedule II controlled substances.

(Amended Stats. 1997, Chapter 549)

4071.1. Electronic Prescription Entry Into Pharmacy or Hospital Computer

(a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent"is a person licensed or registered under Division 2 (commencing with Section 500). This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(b) Nothing in this section shall reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.

(c) No dangerous drug or dangerous device shall be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.

(Added Stats. 2000, Chapter 293)

4072. Oral or Electronic Transmission of Prescription - Health Care Facility

(a) Notwithstanding any other provision of law, a pharmacist, registered nurse, licensed vocational nurse, licensed psychiatric technician, or other healing arts licentiate, if so authorized by administrative regulation, who is employed by or serves as a consultant for a licensed skilled nursing, intermediate care, or other health care facility, may orally or electronically transmit to the furnisher a prescription lawfully ordered by a person authorized to prescribe drugs or devices pursuant to Sections 4040 and 4070. The furnisher shall take appropriate steps to determine that the person who transmits the prescription is authorized to do so and shall record the name of the person who transmits the order. This section shall not apply to orders for Schedule II controlled substances.

(b) In enacting this section, the Legislature recognizes and affirms the role of the Department of Health Services in regulating drug order processing requirements for licensed health care facilities as set forth in Title 22 of the California Code of Regulations as they may be amended from time to time.

(Amended Stats. 1997, Chapter 549)

4073. Substitution of Generic Drug - Requirements and Exceptions

(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute,"or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark.

this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber. The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand. Notwithstanding any provision in this section, the prescriber's address, telephone number, category of professional licensure, or federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.

(3) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(c) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be reduced to writing by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. The date of issue of the prescription and all the information required for a written prescription by subdivision (b) shall be included in the written record of the prescription. The pharmacist need not reduce to writing the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient if that information is readily retrievable in the pharmacy. Pursuant to authorization of the prescriber, any employee of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the employee of the prescriber transmitting the prescription.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Notwithstanding any provision of subdivisions (b) and (c), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

(f) In addition to the prescriber's record required by Section 11190, any practitioner dispensing a controlled substance classified in Schedule II in accordance with subdivision (b) of Section 11158 shall prepare a written record thereof on the official forms issued by the Department of Justice, pursuant to Section 11161, and shall transmit the original to the Department of Justice in accordance with any rules that the department may adopt for completion and transmittal of the forms.

(Amended Stats. 2002, Chapter 536)

11164.5. Electronic Prescriptions or Orders to Pharmacies and Hospitals

(a) Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California State Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision.

(b) Notwithstanding Section 11164, if approved pursuant to subdivision (a), a pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance classified in Schedule II, III, IV, or V shall not be required to reduce that prescription or order to writing or to hard copy form, if for three years from the last day of dispensing that prescription, the pharmacy or hospital is able, upon request of the board or the Department of Justice, to immediately produce a hard copy report that includes for each date of dispensing of a controlled substance in Schedules II, III, IV, and V pursuant to the prescription all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040 of the Business and Professions Code and the name or identifier of the pharmacist who dispensed the controlled substance.

(c) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

(Added Stats. 2000, Chap. 293)

11165. Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. CURES shall be implemented as a pilot project, commencing on July 1, 1997, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies between the two systems.

(b) The CURES pilot project shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or crimi-

Attachment D

110 WEST A STREET, SUITE 1100
SAN DIEGO, CA 92101
P.O. BOX 85266
SAN DIEGO, CA 92186-5266
Public: (619) 645-2400
Facsimile: (619) 645-2489
Direct Dial: (619) 645-2210
E-Mail: Rodney.Lilyquist@doj.ca.gov
June 2, 2003

TO WHOM IT MAY CONCERN:

RE: Opinion No. 03-601

We have received a request from Senator Richard Alarcon for an opinion of the Attorney General on the following questions:

1. Will the State of California be subject to Food and Drug Administration sanctions if it purchases prescription drugs in Canada for its Medi-Cal beneficiaries?

2. Will a California buying co-operative created to purchase prescription drugs in Canada be subject to prosecution by the Food and Drug Administration if it limits the sale of such drugs to its members?

3. Will a California non-profit corporation importing prescription drugs from Canada be subject to prosecution by the Food and Drug Administration if the distribution of such drugs is limited to its members and their families or those certified by the state or federal government as living at or below the poverty level?

4. Will a sovereign Indian nation in California be subject to prosecution by the Food and Drug Administration if it imports prescription drugs from Canada for its members or for other Indian nations where sovereignty has been recognized by the United States?

5. May such an Indian nation sell Canadian prescription drugs on its reservation or through its Internet website to other residents of California?

6. Will residents of California who take chartered bus trips to Canada to purchase prescription drugs be subject to prosecution by the Food and Drug Administration?

7. Will a city or county in California be subject to prosecution by the Food and Drug Administration if it passes legislation legalizing the importation of prescription drugs from Canada for the use of its residents or those living at or below the poverty level?

8. May the federal government successfully challenge the constitutionality of an initiative measure adopted in California legalizing the importation of prescription drugs from Canada?

9. May public pension funds such as CALPERS or CALSTRS negotiate for Canadian prescription drug prices for their members?

It is the policy of our office to solicit the views of all interested parties prior to issuing an opinion. If you would like to submit comments, a response by July 2, 2003, would be most helpful; materials received after such date will nonetheless be considered. Please address your views to: Deputy Attorney General Gregory Gonot, Post Office Box 944255, Sacramento, CA 94244-2550; telephone (916) 324-7860; or via e-mail Gregory.Gonot@doj.ca.gov.

Issued opinions may be found on the Internet at www.caag.state.ca.us/opinions.

Sincerely,

RODNEY O. LILYQUIST
Senior Assistant Attorney General
Chief, Opinion Unit

For BILL LOCKYER
Attorney General

ROL:jmn

News Release

FOR IMMEDIATE RELEASE

May 22, 2003

For more information contact:
Courtney M. Karzen, Communications and Services Senior Manager
847/698-6227; custserv@nabp.net

NABP, NAPRA Finalize Position Statement to Work Together to Protect Citizens

On May 4, 2003, the National Association of Boards of Pharmacy® (NABP®) announced the finalization of a position statement between the Association and the National Association of Pharmacy Regulatory Authorities (NAPRA) whereby NABP and NAPRA pledge to work together to protect the citizens that each are mandated to serve and to promote compliance with the federal, state, and provincial laws and standards of Canada and the United States, to ensure the safety and integrity of the prescribing drug supply in their respective jurisdictions.

Both associations share the common responsibilities in the regulation of the practice of pharmacists, ensuring public safety, and are committed to working together to advocate the ability and effectiveness of individual member organizations in executing their regulated mandates. Due to an immediate need to address the cross-border movement of prescription drugs, both associations signed an agreement stating in part that "illegal international movement of prescription drugs between Canada and the United States undermines the regulatory systems established in each country to protect consumers. . . ."

(— more —)

"It is important for the American public to understand that there are numerous risks involved with purchasing prescription medications from countries other than where the patient lives including adverse reactions between other prescription medications, over-the-counter drugs, and/or nutritional supplements that could have been recognized had the patient gone to his or her regular pharmacist." warned NABP Executive Director/Secretary Carmen A. Catizone. "Another danger in the illegal purchasing of prescription medications lies in not fully knowing where the medications originated from, ie, these drugs bought via illegal methods could contain incorrect dosages, or be contaminated and/or counterfeit."

NABP is pleased to announce that Barbara A. Wells, executive director of NAPRA, and Carmen A. Catizone formally executed that agreement at NABP's 99th Annual Meeting, May 3-7, 2003, in Philadelphia, PA.

Catizone stated, "We [NABP and NAPRA] believe that due to the explosion of foreign prescription drug importation, it is imperative that we work closely with NAPRA and their provincial and territorial members to tackle the challenges pharmacy regulators face on both sides of the border and protect public safety."

Wells agreed and added, "This joint resolution signals our [both associations'] commitments to work together to support the ability and effectiveness of our member organizations in protecting the citizens each are mandated to serve . . . ."

NABP and NAPRA have worked closely with US Food and Drug Administration on this issue. For more information about the position statement, please contact NABP at 847/698-6227.

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

- 30 -

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

JUN 30 2003

Via Fax and Federal Express

C. Bradley Stevens
President/CEO
CanadianDiscountDrugs
100 Denham Square
Peachtree City, GA 30269

Debbie Stevens
Vice President of Marketing
CanadianDiscountDrugs
1518 B Andrews Avenue
Claybank Plaza
Ozark, AL 36360

Dr. Russell L. Page, Jr.
Registered Agent
Ameri-Can Global
Pharmaceutical Supply, Inc.
1009 Roy Parker Rd.
Ozark, AL 36360

Dr. Russell L. Page, Jr.
Vice President
CanadianDiscountDrugs
1518 B Andrews Avenue
Claybank Plaza
Ozark, AL 36360

Syretha Page
Registered Nurse
Sales/Marketing
CanadianDiscountDrugs
1518 B Andrews Avenue
Claybank Plaza
Ozark, AL 36360

Dear Mr. Stevens, Mrs. Stevens, Dr. Page, and Mrs. Page:

The Food and Drug Administration (FDA) has learned that you, CanadianDiscountDrugs, and Ameri-Can Global Pharmaceutical Supply, Inc. (collectively, "CanadianDiscountDrugs" or "you") are assisting United States consumers in obtaining prescription drugs from Canada. Specifically, consumers can use your fax machines, your computer equipment, or your Web site, canadiandiscountdrugs.com, to send U.S. prescriptions, credit card information, and paperwork (including a "Customer Agreement & Order Form" and a "Health Profile") to Total Care Pharmacy in Calgary, Alberta, Canada. According to information provided by you, a Canadian physician reviews the prescription and customer's medical history, and Canadian drugs are then shipped by Total Care Pharmacy directly to the U.S. consumer. As discussed in detail below, your actions violate the Federal Food, Drug and Cosmetic Act (FD&C Act or Act), 21 U.S.C. § 301 et seq. Your actions also present a significant risk to public health, and you mislead the public about the safety of the drugs obtained through CanadianDiscountDrugs.

Legal Violations

Virtually every shipment of prescription drugs from Canadian pharmacies to consumers in the U.S. violates the Act. Even if a prescription drug is approved in the U.S., if the drug is also originally manufactured in the U.S., it is a violation of the Act for anyone other than the U.S. manufacturer to import the drug into the United States (21 U.S.C. § 381(d)(1)). We believe that virtually all drugs imported into the U.S. from Canada by or for individual U.S. consumers also violate U.S. law for other reasons. Generally, such drugs are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. § 353(b)(2)), and/or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Thus, their shipment into the U.S. from Canada violates the Act. See, e.g., 21 U.S.C. 331(a), (d), (t).

The reason that Canadian or other foreign versions of U.S.-approved drugs are generally considered unapproved in the U.S. is that FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Frequently, drugs sold outside of the U.S. are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved. 21 U.S.C. § 355.

In order to ensure compliance with the Act when they are involved in shipping prescription drugs to consumers in the U.S., businesses and individuals must ensure, among other things, that they only sell FDA-approved drugs that are made outside of the U.S. and that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. They must also ensure that each drug meets all U.S. labeling requirements, including that it bears the FDA-approved labeling. 21 C.F.R. § 201.100(c)(2). The drug must also be dispensed by a pharmacist pursuant to a valid prescription. 21 U.S.C. § 353(b)(1).

Practically speaking, it is extremely unlikely that a pharmacy could ensure that all of the applicable legal requirements are met. Consequently, almost every time an individual or business ships a prescription drug from Canada to a U.S. consumer, the individual or business shipping the drug violates the FD&C Act. Moreover, individuals and businesses, such as CanadianDiscountDrugs and its responsible personnel that cause those shipments also violate the Act. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited...").

For your information, under FDA's Personal Importation policy, as a matter of enforcement discretion in certain defined circumstances, FDA allows consumers to import otherwise illegal drugs. However, this policy is not intended to allow importation of foreign versions of drugs of which there is a FDA-approved version. This is especially

true when the foreign versions of such drugs are being "commercialized" to U.S. citizens through operations such as yours. Moreover, the policy simply describes the agency's enforcement priorities. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States. See FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importations.

FDA's Public Health Concerns and Your Misleading Statements about Drug Safety

You also make misleading statements to consumers about the safety of the drugs purchased through CanadianDiscountDrugs and the legitimacy of your operation. A brochure which you distributed claimed that "[a]ll medications offered are also approved by the U.S. Food and Drug Administration." The brochure also stated that Total Care Pharmacy was inspected "by Health Canada at the request of the U.S. Food and Drug Administration." Canadiandiscountdrugs.com purports to answer the question, "How do I know prescription medications from Canada are of the same safety and quality as those in the United States?" Canadiandiscountdrugs.com also states that Total Care Pharmacy is "one of the most respected Canadian pharmacies serving the U.S. market." These statements imply that your operation is legal and endorsed by the U.S. government, and that the drugs purchased through you are safe.

These statements are misleading. As discussed above, your operation is illegal. In addition, prescription drugs purchased from foreign countries generally are not FDA-approved, do not meet FDA standards, and are not the same as the drugs purchased in the United States. Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. Because the medications are not subject to FDA's safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use. These risks are exacerbated by the fact that many of the products you are soliciting United States consumers to buy are indicated for serious medical conditions.[1] At least one of them presents risks that FDA has determined warrant special patient labeling.[2]

FDA is also very concerned about the importation of prescription drugs from Canada and other foreign countries because, in our experience, many drugs obtained from foreign sources that purport or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Recent examples of counterfeit products entering the U.S. marketplace also raise substantial safety questions about drugs from foreign countries.

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[1] For example, on canadiandiscountdrugs.com, you offer prescription drugs indicated for use in treating cancer (tamoxifen), HIV (abacavir sulfate), and hypertension (irbesartan).

[2] For example, on canadiandiscountdrugs.com, you offer abacavir sulfate (Ziagen), a carbocylic nucleoside reverse transcriptase inhibitor indicated for the treatment of HIV.

Moreover, there is a possibility that drugs which come to U.S. consumers through Canada or purport to be from Canada may not actually be Canadian drugs. In short, drugs delivered to the American public from foreign countries may be very different from products approved by FDA and may not be safe and effective. For all of these reasons, FDA believes that operations such as yours expose the public to significant potential health risks.

Action Needed

This letter is not intended to identify all of the ways in which your activities violate United States law. It is your responsibility to ensure that you are in compliance with applicable legal requirements.

Please notify this office in writing within fifteen (15) working days of your receipt of this letter of the specific steps you will take to assure that your operations are in full compliance with United States law. Please address your correspondence to Mr. Melvin Szymanski, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 5600 Fishers Lane, Rockville, MD 20857. If you do not promptly correct your violations, FDA may take legal action without further notice. Possible actions include seizure and/or injunction. Further, federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Sincerely,

David J. Horowitz, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Via Fax and/or Federal Express

Cc: Dr. Russell L. Page, Jr.
CanadianDiscountDrugs
811 Roy Parker Rd.
Ozark, AL 36360

Jerry Moore
Executive Director
Alabama State Board of Pharmacy
#1 Perimeter Park South
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Administrator, Domain
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Chairman
Alabama State Board of Medical Examiners
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Danièle Dionne
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Attachment E

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Medical Board of California
California State Board of Pharmacy

Joint Task Force on Prescriber Dispensing

Meeting Summary

DATE: May 27, 2003

TIME: 2:00 p.m. – 5:00 p.m.

LOCATION: Embassy Suites – Granada Room
El Segundo, CA 90245

Joint Task Force Members:
Steven B. Rubins, M.D., Co-Chair, MBC
John Jones, R.Ph., Co-Chair, Board of Pharmacy
Lorie Rice, Public Member, MBC
Stan Goldenberg, R.Ph., Board of Pharmacy

Staff Present:
Ron Joseph, Executive Director, MBC
Patricia Harris, Executive Officer, Board of Pharmacy
Ronald Diedrich, Liaison Deputy Attorney General for the Board of Pharmacy
Paul Riches, Legislative Analyst, Board of Pharmacy

Call to Order/Introductions:

Chairs Rubins and Jones called the meeting to order at 2:00 p.m. Each task force member introduced himself or herself as did the audience participants.

Purpose and Goals of the Task Force

It was stated that the purpose and goals of the task force was to evaluate the prescriber dispensing law (Business and Professions Code section 4170) to determine if it is still relevant to today's practice and to identify those areas of law that needed to be clarified or updated to ensure public protection. Specific areas that should be addressed were the commingling of drugs by physician groups for common use, potential conflicts of interest and the jurisdictional authority of the Medical Board of California and the Board of Pharmacy.

Park Medical Pharmacy v. San Diego Orthopedic Associates, Inc. **(2002) 99 Cal. App.4th 247**

As background information, the task forced reviewed this decision. In 1992, Park Medical Pharmacy brought action for declaratory and injunctive relief against San Diego Orthopedic

Associates, Inc., a physicians' corporation, alleging violation of the statute (Bus. & Prof. Code sec. 4170) prohibiting physicians from keeping pharmacies. The Superior court in San Diego County granted summary judgment for the physicians' corporation and the pharmacy appealed. The Court of Appeal held that the physicians did not violate pharmacy law by dispensing drugs to their patients on a for-profit basis.

Review of Business and Professions Code Section 4170

It was explained that current law allows an individual prescriber to dispense prescription drugs to his/her own patient from the prescriber's own stock. The drugs must be necessary for the treatment of the condition for which the prescriber is attending the patient, and a nurse or physician attendant cannot furnish the prescription drugs. However, a nurse may assist, at the prescriber's direction, in the dispensing of such drugs, including handing them to the patient, under the direct supervision and control of the prescriber provided that the prescriber verifies each step performed by the nurse. (57 Op. Attorney Gen.93 (1974)) The law does allow a certified nurse-midwife, a nurse practitioner, or a physician assistant functioning pursuant to a protocol to hand to a patient of the supervising physician and surgeon a properly labeled prescription drug that has been properly prepackaged.

There was agreement that the dispensing prescriber must comply with all the labeling requirements of section 4076, and the recordkeeping requirements of the Pharmacy Law. The pharmacy's dispensing process was explained, including the safeguards established to prevent prescription errors, quality assurance evaluations and the review of every prescription by a pharmacist. The law does allow a prescriber to use a dispensing device as long as the prescriber owns the device and personally dispenses the prescription drugs.

Current law does not authorize a group of physicians to purchase prescription drugs for group dispensing. Only clinics permitted by the Board of Pharmacy may directly purchase drugs for common use.

Recommendations

There was considerable discussion regarding the conflict of interest when a physician dispenses prescription drugs for profit. However, it was noted that the dispensing prescriber is required to offer the patient the option of having the prescription filled at a pharmacy of the patient's choice.

It was suggested that physicians be allowed to dispense from a commingled drug supply if a permit process was established modeled after the Board of Pharmacy's clinic permit (Business and Professions Code sections 4180 and 4190). Another example to this permit process is the licensure of laboratories by Department of Health Services. These laboratories are owned by medical groups and are located in their office. Another proposal was to authorize a pharmacy to place in the prescriber's office an automated dispensing device consistent to what is allowed now in clinics that would provide the patient with increased access to prescription drugs and oversight by a pharmacist.

The task force reached consensus on the following issues: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the recordkeeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, recordkeeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004.

Adjournment

The meeting of the Joint Task Force on Prescriber Dispensing was adjourned at 5:00 p.m.

Attachment F

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
July 2, 2003

Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814

Present: John Jones, Chair and Board President
Stan Goldenberg, Board Member
Don Gubbins, Board Member
Bill Powers, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Ron Diedrich, Liaison Deputy Attorney General
Enforcement Staff

Call to Order

Enforcement Committee Chair John Jones called the meeting to order at 9:30 a.m.

Reimportation of Prescription Drugs from Canada

Committee Chair John Jones began the discussion by stating that Senator Alarcon requested an opinion from the Attorney General on several questions regarding the importation of prescription drugs from Canada. He stated it was unknown when the opinion would be published and none of the questions were about the use of storefront facilities by consumers to access prescription drugs from Canada.

It was also stated that importation of drugs from foreign countries is a federal issue and within the purview of the FDA. There is a provision that has been proposed as part of the pending Medicare legislation that would allow for the reimportation of drugs from Canada. Although current federal law allows for reimportation, the secretary of Health and Human Services must approve such action and has chosen not to do so.

California Pharmacy law specifies that the board's primary purpose is consumer protection. It is the board's discretion as to what action it will take. The board will investigate any consumer complaint that involves a prescription drug from Canada irrespective of how it was obtained. The board is concerned that consumers have access to safe prescription drugs. It is not the board's position to pursue complaints for economic or competitive reasons. Moreover, a business has the ability to pursue a private right of action for unfair businesses practices under Business and Professions Code section 17200.

It was expressed that the Board of Pharmacy should advocate to the FDA that it move forward to allow other entities to import prescription drugs from Canada. There is currently a mechanism in place for manufacturers. It was argued that a similar licensing process could be implemented for wholesalers and pharmacies that would ensure the safety of the prescription drugs being imported from Canada.

Proposed Modification to Quality Assurance Regulation

At the April Board meeting, the Enforcement Committee discussed the proposed language that was submitted to amend CCR 1771(c) regarding the notification of the patient and prescriber when a prescription error has occurred. It was requested that this issue be returned to the Enforcement Committee with direction to the stakeholders to develop language to address those situations when a patient has not ingested the medication. The stakeholders recommended the following modifications:

(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless ~~the~~ **a** pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall ~~immediately~~ **as soon as possible, and working in collaboration with the prescriber or the prescriber's agent, ~~or if unavailable, another prescriber then treating the patient,~~** communicate to the patient **or the patient's representative or care provider** ~~and the prescriber~~ the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error. **The provisions of this subsection (c) shall only apply to medication errors in which the patient took, or was administered a drug in error.**

Concern was expressed that the language did not include those situations where the prescriber should be notified if there is significant harm because the patient's therapy was delayed as a result of the error. Clarification was sought as to the distinction between notifying the prescriber "immediately" or "as soon as possible." An example was provided in the hospital setting where a patient may have been administered a drug in error at night and the harm was not significant. In this situation, the pharmacist could notify the prescriber the next day. However, in some cases, the pharmacist should notify the prescriber immediately because there has been significant harm, even if happened at night. The proposed language allows the pharmacist to use his/her professional judgment to determine the appropriate process of notification.

It was also noted that the language should be clarified regarding patient notification because proposed modifications appear to require that the patient be notified in collaboration with the prescriber. While it is usually the patient that notifies the pharmacist in the community setting, the language was not intended to require the pharmacist to notify the patient in collaboration with the prescriber.

The committee recommended that the Board of Pharmacy amend CCR, title 16, section 1711(c) as discussed with the changes to the language that would clarify the concerns discussed about the delay in therapy and the patient notification.

Proposed Regulation of Wholesale Drug Transactions - CCR 1784 and 1785

Supervising Inspector Judi Nurse gave an overview regarding bid contract diversion in California. Pharmacies purchase "bid contract" drugs at special prices and then through a common ownership transfer the drugs to its wholesale facility to be resold to other wholesalers. Often times, there is no record for these drug transaction. The drugs are resold several times through many wholesalers and many states in largely undocumented transactions that are impossible to trace. This "gray market" system has allowed for counterfeiting which is the dilution, mislabeling or adulteration of the drug. The unscrupulous companies can turn one shipment of injectable medications into many by watering down the drugs and reproducing the packaging.

Comments were made that the proposed regulation sections impede legitimate business transactions and modifications were suggested. It was also stated that the PDMA allows for intra-company sales, which may be contrary to the proposed section 1784. While the board has been using Nevada as its model for the regulatory framework, it was suggested that the committee might want to review the Florida legislation. This new legislation identifies a list of drugs that require a statement of prior sales.

Chair John Jones requested interested parties to submit proposed language for continued discussion by the Enforcement Committee.

Request for Pharmacy Records by Authorized Officers of the Law

Executive Officer Patricia Harris stated that it has been brought to the board's attention that pharmacies are choosing not to provide prescription records when requested by an authorized officer of the law engaged in an official investigation. Whether to provide the record or not, is a decision that the licensee must make. The board does not advise licensees in this regard.

However, there is some misinformation that is being given to the officers as to why the pharmacy will not release the records without an investigative subpoena. One reason is that the Board of Pharmacy requires an investigative subpoena to document the release of the records and without it, the pharmacy will be cited for violation of pharmacy law.

This is not true. When an officer takes prescription record(s), the pharmacy should be given a receipt identifying the records. If a board inspector should ever ask for the same records, the pharmacy should be able to produce the receipt to document release of the records to an authorized officer of the law. Concern was expressed that receipts are not detailed enough to document to an inspector what records may have been released. Response was provided that this is a concern that the pharmacy should seek legal counsel. It was suggested that the board write a newsletter article on this issue.

Delivery of Prescription Drugs Pursuant to Business and Professions Code section 4059.5

It was requested that the board consider its interpretation of Business and Professions Code section 4059.5 to allow for the delivery of prescription drugs to a secured area when a pharmacy is closed. The law requires that the dangerous drugs must be delivered to the licensed premises and signed for and received by the pharmacist-in-charge or, in his or her absence, another pharmacist designated by the pharmacist-in-charge.

It was presented that due to various local ordinances and environmental factors, delivery of prescription drugs must take place after the pharmacy is closed. It was requested that the board consider the delivery of the prescription drugs to a secured area as the prescription drugs still being in transit. It is when the pharmacy takes possession of the drugs that the drugs would be considered delivered to the pharmacy in compliance with 4059.5. The wholesaler would be responsible until such time that the pharmacy took possession.

The committee discussed this request and agreed that it would recommend that the board consider such an interpretation and the statute be changed consistent with the interpretation. However, once the prescription drugs were delivered to the "secured area", the drugs would no longer be in "transit." The pharmacy would then be responsible for the prescription drugs.

Off-Site Order Entry of Hospital Medication Orders

Dr. Cacciatore of CardinalHeath presented a proposal to license a pharmacy service center in California. This would be an office-based, licensed pharmacy staff with experienced hospital pharmacists. The hospital would transmit new orders to the service center after the hospital pharmacy closes or when needed via fax or digital imaging. Pharmacists at the pharmacy service center would remotely access the hospital computer system and review orders, perform prospective drug use review, and approve orders within 60 minutes. Pharmacists would also be available via a toll free number to answer medication questions from nursing and medical staff.

The pharmacy service center would have access to the hospital pharmacy computer system through a secure, virtual private network. The pharmacy service center would

also enter into a Business Associate agreement with the hospital and would be in full compliance with HIPAA and state privacy laws.

It was noted that Business and Professions Code section 4071.1 allows for a pharmacist to electronically enter a prescription or order into a hospital's computer from any location outside the pharmacy or hospital with the permission of the pharmacy or hospital. Health and Safety Code section 11164.5 allows for electronic data transmission or computer entry of prescriptions for controlled substances if authorized by federal law and with the approval of the Board of Pharmacy and the Department of Justice.

Dr. Cacciatore stated that CardinalHealth will be submitting a community pharmacy application for licensure of this facility. He also stated that he will submit a written request for approval Health and Safety Code section 11164.5 to enter in the hospital computer system controlled substances. He will be submitting a request for approval to the Department of Justice and the Board of Pharmacy.

The committee agreed that the licensure of this facility as a community pharmacy was appropriate and directed staff to work with the Department of Justice regarding the approval process as provided in the Health and Safety Code for controlled substances. The committee also agreed to recommend that the executive officer be delegated the authority as part of the licensing process to approve these requests.

Report on the MBC/Board of Pharmacy Joint Task Force Meeting on Prescriber Dispensing

Chair John Jones reported that the Medical Board of California and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the recordkeeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, recordkeeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

He stated that the task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004.

Implementation of federal HIPAA Requirements

The Enforcement Committee was provided with the NABP document prepared on the frequently asked questions regarding HIPAA. Specifically the questions are: What protected health

information can be disclosed to pharmacy inspectors? What information can inspectors access? and Are inspection activities included in the accounting of disclosures? In addition, a detailed description of the board's "Statement of Authority" was provided. This document will be used for a newsletter article and the sections of law specifying the board's authority will be added to the board's inspection report.

Pharmacists Recovery Program

It was reported that Maximus, Inc. is the new contractor for the board's Pharmacists Recovery Program, effective July 1, 2003. Leslie Hanover is the board's case manager. She is a licensed Marriage Family Therapist with experience in mental health and substance abuse since 1986. The 800 number has been transferred to the new contractor. The participants and the professional associations have been notified of the new contractor. An article will also be published in the next newsletter.

Strategic Objectives for 2003/04

Chair John Jones identified the board's strategic objectives for 2003/04 that were developed during the board's strategic planning session at its April meeting.

Discussion of Issue not Noticed on the Agenda

CPhA expressed concern that the Board of Pharmacy is requiring pharmacies to dispense and label medical supplies and OTC drugs in accordance with the requirements for prescription drugs because Medi-Cal requires that they be dispensed upon a prescription for reimbursement. It was noted that DME providers dispense these same medical supplies without meeting the same prescription requirements as pharmacies or with a pharmacist oversight. The Enforcement Committee agreed to research this issue for further discussion at the next Enforcement Committee meeting in September.

Agenda Item G

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Enforcement Team Meeting

July 2, 2003
1:30 p.m. – 4:00 p.m.

Present: Committee Chair and Board Member John Jones
Board Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors
Enforcement Staff

Announcements/Introductions

Committee Chair John Jones called the meeting to order at 1:30 p.m.

Quality Improvement Efforts

Supervising Inspector Judi Nurse reported on the implementation of the Routine Compliance Inspection Program. For this fiscal year, 1,941pharmacies have been inspected. Of these, 121 cases were opened (6%). Since the inception of the program in July 2001, the total number of inspections has reached 5,253. This includes the inspection of over 574 probation and PRP participants.

Enforcement Analyst Cassandra Kearney reported on the consumer satisfaction survey. It was reported that 2 surveys were received out of the 51 postcards sent. The team discussed various options to increase the responses. Ms. Kearney will report at the September meeting the implementation of these changes.

Supervising Inspectors Robert Ratcliff and Judi Nurse noted the many significant inspector accomplishments since the last meeting. They commended Supervising Inspector Dennis Ming and inspectors for their extraordinary efforts to implement the compounding pharmacy licensure and inspection program.

Supervising Inspector Robert Ratcliff reported on the status of completed cases since the last team meeting. He displayed the workload for each team and their significant progress. There are 878 pending complaints/investigations. Of these, 461 reports have been submitted and 417 cases are assigned for mediation or investigation. Supervising Inspector Ratcliff reported that cases are aging beyond the targeted time frames for closure. He provided case status reports to each inspector with deadlines.

The Enforcement Committee members John Jones and Stan Goldenberg acknowledged the efforts of the enforcement staff and recognition by other states of the board's many accomplishments, which are attributed to the quality of the board's enforcement program and staff.

Evaluation of the Team Concept

Ms. Herold stated that the 2001/03 collective bargaining contract for board inspectors established a joint labor-mangement committee on inspector workload issues. There have been two meetings, one in December 2002 and one in late February 2003. The inspector members on this committee have provided updates to other board inspectors about the discussions. During the February meeting, the inspector representatives requested a formal evaluation of the team concept by the board. Whereas management believes that discussions about team activities has been an integral component of every quarterly Enforcement Team meeting since 1998, the board agreed to provide an opportunity at this meeting for inspectors and all other staff to provide information on the team structures. To facilitate the discussion, the Enforcement Team meeting packet contained a copy of the team charters for each of the teams that was created by a group of board inspectors and managers five years ago.

Additionally, a new organizational chart was distributed showing current team assignments and designating one supervising inspector as the supervisor for each team. The addition of two new supervising inspector positions in February has made it possible to have a supervising inspector oversee each team, with the Compliance Team staff being divided into two subteams each headed by a supervising inspector. The supervisors will work closely with each assigned team member to strengthen performance, assist with difficult assignments and integrate team meetings, training and communication.

President Jones started the discussion stating that the board's inspectors have made considerable strides in integrating the new compounding inspections with the compliance inspections. During the board's outreach programs at local association meetings, he stated that one recurrent comment is that board inspectors are again out in the field, but that there seems to be a different inspector each time conducting a specific pharmacy's inspections. President Jones added that he believes this is a significant strength of the new system because among other benefits, it keeps licensees from becoming too cozy with a specific inspector. The Santa Barbara area is still talking about the days the board inspectors all came into the area and did inspections. He commended board staff for these activities. He also discussed at length the need for the board's enforcement program to perform continuous evaluations of activities and processes so that enhanced consumer protection is achieved. With budget limitations this will be essential.

From the inspectors were two comments -- one was the team charters were no longer distributed to new inspectors, and haven't been distributed to inspectors hired in the last three years. However, it was explained that while the charters may not have been distributed, considerable discussion occurs during the employment interviews and subsequent training about the role and duties of each team, and the fact that the board performs its work in a team model.

The second comment was that with the team concept, occasionally one inspector will be assigned to inspect the same facility as another inspector who is investigating a complaint. President Jones asked whether the inspector in such a case had contacted a supervisor for guidance, but the inspector had not. Supervising Inspector Ratcliff encouraged such inquiries to a supervisor and added that in this case, there was a reason why two inspectors had been assigned to the same facility.

Ms. Herold stated that if there are other comments on the team concept, please send them in. Refinements to team operations are an ongoing process.

Discussion of Enforcement Committee Meeting

The Enforcement Team discussed the agenda items from the Enforcement Committee meeting.

Adjournment

Committee Chair John Jones adjourned the meeting at 4:15 p.m.

Attachment H

Board of Pharmacy Enforcement Statistics
Fiscal Year 2002/2003

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 02/03
Complaints/Investigations					
Initiated	380	292	444	389	1505
Closed	264	331	349	269	1213
Pending (at the end of quarter)	749	715	827	948	948
Cases Assigned & Pending (by Team) as reported July 2, 2003					
Compliance Team	239	217	245	287	
Drug Diversion/Fraud	128	146	148	154	
Mediation Team	187	154	187	178	
Probation/PRP	71	71	105	116	
Enforcement	190	208	209	169	
Site Inspections					
Performed	745	696	585	613	2639
Corrections Ordered	426	387	275	268	
Application Investigations					
Initiated	127	120	121	36	404
Closed					
Approved	103	75	94	53	325
Denied	9	0	2	3	14
Total*	112	79	130	60	381
Pending (at the end of quarter)	150	187	177	152	152
Citation & Fine					
Issued	136	193	253	123	705
Abated	59	123	97	166	445
Total Fines Collected	$79,850.00	$77,975.00	$61,075.00	$180,875.00	$399,775.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2002/2003

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 02/03
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	63	23	36	21	143
Pleadings Filed	31	24	10	16	81
Pending					
Pre-accusation	54	42	65	69	69
Post Accusation	96	91	74	58	58
Total	184	180	142	130	130
Closed**	40	40	31	34	145
Revocation					
Pharmacist	3	2	4	3	12
Pharmacy	1	2	2	2	7
Other	5	4	8	4	21
Revocation,stayed; suspension/probation					
Pharmacist	6	4	3	3	16
Pharmacy	0	1	2	0	3
Other	0	0	0	1	1
Revocation,stayed; probation					
Pharmacist	4	4	4	4	16
Pharmacy	1	1	0	2	4
Other	1	0	0	1	2
Suspension, stayed; probation					
Pharmacist	1	0	0	0	1
Pharmacy	1	0	0	1	2
Other	0	0	0	0	0
Surrender/Voluntary Surrender					
Pharmacist	3	1	3	4	11
Pharmacy	0	0	1	1	2
Other	6	4	1	1	12
Public Reproval/Reprimand					
Pharmacist	1	2	1	6	10
Pharmacy	0	1	1	0	2
Other	0	0	0	0	0
Cost Recovery Requested	$85,166.25	$65,605.00	$122,039.95	$108,953.50	$381,764.70
Cost Recovery Collected	$25,786.78	$61,265.41	$59,140.34	$48,375.21	$194,567.74

* This figure includes Citation Appeals

Board of Pharmacy Enforcement Statistics
Fiscal Year 2002/2003

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 02/03

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2002/2003

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 02/03
Probation Statistics					
Licenses on Probation					
Pharmacist	116	133	141	132	132
Pharmacy	26	26	27	28	28
Other	25	25	24	21	21
Probation Office Conferences	18	10	16	22	66
Probation Site Inspections	71	65	53	39	228
Probationers Referred to AG for non-compliance	1	2	0	2	5

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program

Program Statistics					
In lieu of discipline	0	1	0	0	1
In addition to probation	1	3	1	5	10
Closed, successful	3	0	3	3	9
Closed, non-compliant	2	3	5	4	10
Closed, other	0	0	1	0	1
Total Board mandated Participants	50	50	49	50	50
Total Self-Referred Participants*	15	15	15	15	15
PRP Site Inspections**	29	1	6	8	44
Treatment Contracts Reviewed	31	37	26	23	26

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of March 31, 2003.

Citation and Fine Committee Statistics for July 1, 2002 – June 30, 2003

Total cases reviewed by Citation and Fine Committee	Citations Issued with fines	Citations without fines
391	613	295

Subjects referred to:			Subjects closed no further action
AG	Add. Invest.	Add. Insp.	
2	4	0	191

Average number of days for investigation process

Case open to citation issued	Request to Office Conference	Appeal request to hearing date
228 days	31 days	Data not available

Contested Citations Office Conference

Requested	Scheduled	Appeared	Affirmed	Amended	Dismissed	Withdrawn
124	102	97	60	17	20	5

- The committee held 19 meetings.
- The committee held 20 office conferences.

- Total money amount of citations issued FY 02/03 $407,775.00
- Total money amount of internet citations issued FY 02/03 $1,531,000.00

Contested Citation Appeals

Received	Settled	Sent to AG	Heard
43	26	5	1

Citation Breakdown by license type

RPH with fine	RPH no fine	RPH closed	PHY with fine	PHY no fine	PHY closed	PIC with fine	PIC no fine	PIC closed
241	165	84	252	208	58	87	33	13

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	27.8	1716 - Variation from prescription	21	4115/1793.7 – Pharmacy technician license req. /Requirements for PHY with techs	13.3
1707.2 – Duty to consult	8.6	1714 (b) – Operational standards & security	9.8	1714(d) – Operational standards and security	12.3
1714(d) – Operational standards and security	7.6	1761- Erroneous or uncertain prescriptions	6.6	1707.2 – Duty to consult	6.5
1761- Erroneous or uncertain prescriptions	5.8	4115/1793.7 – Tech activities permitted; Req. supervision/Req. for PHY with techs	5	1715 - Self-Assessment of a pharmacy by the Pharmacist-in-Charge	5.8
4076/4077- Rx container labeling requirements	5.1	1707.2 – Duty to consult	4.6	4081/4332/4333 – Records of dangerous drugs.	5.8
4081/4332/4333 – Records of dangerous drugs.	2.7	4081/4332/4333 – Records of dangerous drugs	3.1	4125/1711 Quality Assurance	5.2
4115/1793.7 – Pharmacy technician/ Requirements for Pharmacies Employing Pharmacy Technicians	2.4	1764/56.10 – Unauthorized disclosure of Rx	2.6	1716 - Variation from prescription	5.2
1764/56.10– Unauthorized disclosure of Rx	2.1	4076/4077 - Rx container labeling requirements	2.4	1761- Erroneous or uncertain prescriptions disclosure of Rx	3.6
4059.5 - Who may order dangerous drugs	1.7	4067 - Internet: Dispensing Dangerous drugs or Devices without prescription	2.4	4076/4077 - Rx container labeling requirements	3.6
1716.2 - Records requirements-compounding for future furnishing	1.7	4125/1711 – Quality Assurance	2.2	1716.2 - Records requirements-compounding for future furnishing	3.6

Attachment I

Quarterly Report
FY 2002 - 03
Final Report

July 2003

Enforcement

Goal

Exercise oversight on all pharmacy activities.

Implementation Responsibility

The Enforcement Committee and Staff

Strategic Objectives		Timeline
1. Meet performance expectations of 90 days for complaint mediations and investigations and 6 months for drug diversion investigations that require an audit.		July 2003
10/02	*Reported data at October Board Meeting, 346 cases are pending and of those, 112 are over 90 days and 51 are over 180 days.*	
1/03	*Reported data at January Board Meeting, 353 cases are pending and of those, 94 are over 90 days and 34 are over 180 days.*	
4/03	*Reported data at April Board Meeting, 444 cases are pending and of those, 72 are over 90 days and 68 are over 180 days.*	
7/03	*Reported data at July Board Meeting, 417 cases are pending and of those, 80 cases are over 90 days and 72 are over 180 days.*	
2. Continue active recruitment of inspectors so that all authorized inspector positions remain filled.		July 2003
9/02	*Developed examination questions for inspector and supervising inspector exams. Supervising inspector exam scheduled for December 2002, anticipated inspector exam in January 2003.*	
12/02	*Held supervising inspector examination and interviewed 6 applicants.*	

Strategic Objectives		Timeline
12/02	*Received approval from DPA for inspector reclassification to supervisor.*	
1/03	*Sent contact to supervising inspector applicants for employment interview.*	
3/03	*Held inspector civil service examination.*	
4/03	*Hired two new supervising inspectors.*	
4/03	*Two inspector positions are vacant – positions will not be filled pending decision on 10% reduction of personnel services to avoid possible employee lay offs.*	
6/03	*Received hiring freeze for the two vacant inspector positions. Positions will not be filled until decision is made regarding 10% reduction plan of personnel services.*	
3. Reduce enforcement prosecution time to one year from the date the board refers the case to the Attorney General's (AG) office by actively managing cases and preparing boilerplate language for draft accusations and stipulations.		July 2003
9/02	*Reported in Sunset Report that it takes an average of 188 days for AG's Office to prepare a pleading (this is 52 days longer than reported in the board's last Sunset Report) and once filed 395 days to resolve the case. This process is now 131 days longer.*	
9/02	*Continued active monitoring and case management – requested status reports.*	
12/02	*Due to anticipated AG deficiency, cases are being reviewed for priority (potential harm to public) for continued prosecution – less serious violations are being withdrawn and referred to the Citation and Fine Committee.*	
4/03	*Continued active monitoring and case management – case data reported at board meeting.*	
7/03	*Continued active monitoring and case management – case data reported at board meeting.*	
4. Seek legislation to mandate that the Board of Pharmacy perform periodic inspections of all board-licensed facilities.		January 2004

Strategic Objectives	Timeline
9/02 *Made this recommendation in board's report to the Joint Legislative Sunset Review Committee (JLSRC).*	
4/03 *JLSRC did not propose as a recommendation.*	
5. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.	July 2003
7/02 *Submitted a budget change proposal for ongoing augmentation of $300,000.*	
9/02 *Identified as a recommendation in board's report to the Joint Legislative Sunset Review Committee.*	
10/02 *Department of Finance disapproved the budget augmentation request.*	
12/02 *Re-evaluated cases pending at AG's Office to withdraw less egregious violations for referral to Cite and Fine Committee.*	
1/03 *Requested board approval for AG deficiency request (consistent with current board position).*	
7/03 *Submitted a budget change proposal for ongoing augmentation of $300,000.*	
6. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.	January 2004
7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.	July 2003
9/02 *Withdrew budget change proposal based on Department of Finance directive that it would not approve new or expansion of programs.*	
9/02 *Did not pursue an 800 number for "Notice to Consumer" poster because of fiscal constraints.*	
8. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 Reports).	January 2003

Strategic Objectives		Timeline
9/02	*Began internal evaluation of CURES data. Met with other CURES agencies. Trained staff person on program. Will pursue request to receive CURES data directly from contractor.*	
10/02	*Began review of 1782 reporting program.*	
2/03	*Developed data base program and will field test with licensees.*	
7/03	*Will follow-up field test of program with licensee.*	
7/03	*CURES data now reported to Dept. of Justice. Access to data has improved; however DOJ has not transferred 6 months of data due to "error" issues.*	
9.	Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.	January 2003
10/02	*Presentation on CURES to Los Angeles District Attorney.*	
10/02	*Initiated plan to reinstitute CURES workgroup meetings to identify contract needs, target and coordinate investigation and implement new provision of AB 2655.*	
10/02	*Began development of implementation plan and identify participants.*	
11/02	*Held CURES work group meeting.*	
12/02	*Began development of new 1782 reporting program on ACCESS database.*	
1/03	*Met with Special Assistant Attorney General regarding CURES.*	
4/03	*Held workgroup meeting for demonstration of new reporting program.*	
7/03	*Plan quarterly meetings for 2003/04.*	
10.	Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.	January 2004

Strategic Objectives		Timeline
11. Perform a comprehensive review of the electronic prescribing laws related to the dispensing of controlled substances and dangerous drugs to determine those areas of law that need modification.		January 2004
	9/02 *Issued a compliance guide on Electronic Signatures.*	
	3/03 *Compliance guide was published in board's newsletter.*	
12. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.		January 2004
	8/02 *Initiated discussion with California Pharmacists Association (CPhA) and the California Society of Health System Pharmacies (CSHP). Inaugural presentation at CPhA Annual Meeting in February 2003.*	
	9/02 *Sought suggested presentation areas: review of board, update on new laws and proposals and identified compliance issues.*	
	12/02 *Received request for CE program from CSHP – local chapter in Sonoma County.*	
	12/02 *Developed program for CPhA Annual Meeting to be presented March 1, 2003.*	
	3/03 *Presented CE program at CPhA annual meeting.*	
	4/03 *Presented CE program at San Diego local pharmacists association meeting.*	
	5/03 *Presented CE program at Orange County and Long Beach local pharmacists association meetings.*	
	6/03 *Present CE program to the Santa Rosa local pharmacists association.*	
13. Explore the options for restitution to the consumer for prescription error consumer complaints.		January 2003
	7/02 *Board voted not to pursue a restitution program for consumers because the award of restitution is within the purview of the civil court system and the board did not want to interject itself in this matter as it lacks the*	

Strategic Objectives		Timeline
	resources and knowledge to award damages to consumers who are harmed due to a prescription error.	
9/02	*Reported board action to Joint Legislative Sunset Review Committee.*	
10/02	*Completed.*	

Ongoing Objectives

14. Mediate consumer complaints.

9/02	*Reported in Sunset Report that the board has received 5,205 complaints during the last 4 years, a 153 % increase from the previous Sunset Report.*
10/02	*Consumer complaint data for FY 02/03 reported at October Board Meeting.*
1/03	*Consumer complaint data for FY 02/03 reported at January Board Meeting.*
4/03	*Consumer complaint data for FY 02/03 reported at April Board Meeting.*
7/03	*Consumer complaint data for FY 02/03 reported at July Board Meeting.*

15. Investigate consumer complaints and other alleged violations of pharmacy law.

10/02	*Investigation case data for FY 02/03 reported at October Board Meeting.*
1/03	*Investigation case data for FY 02/03 reported at January Board Meeting.*
4/03	*Investigation case data for FY 03/02 reported at April Board Meeting.*
7/03	*Invesigation case data for FY 03/02 reported at July Board Meeting.*

16. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.

9/02	*Since program inception 7/02, 3,698 inspections have been performed.*
9/02	*Since 7/02 performed 456 inspections, ordered 288 corrections and opened 43 cases.*
12/02	*Since 9/02 performed 680 inspections and opened 54 cases.*
4/03	*Since 12/03 performed 731 inspections and opened 32 cases.*

7/03 *For fiscal year 2002/03, 1,941 compliance inspections were completed, 423 diversion inspections and 582 probationer inspections. Since the program's inception in 7/01, 4,766 routine compliance inspections were completed, 543 diversion and 794 probationers.*

7/03 *For FY 02/03, 1,834 inspections were performed and opened 128 cases (6%).*

17. Prosecute administratively and criminally the most serious violations where drug diversion, self-use or potential or actual public harm resulted from the licensee's actions.

10/02 *Presentation to Los Angeles District Attorney cases of egregious drug diversion activity.*

12/02 *Working with BNE and DEA on criminal prosecution for drug diversion activity.*

18. Manage administrative cases and cases under investigation to resolve them expediently and consistently with the board's enforcement priorities.

9/02 *Case management overview at Enforcement Team Meeting.*

12/02 *Case management overview at Enforcement Team Meeting.*

3/03 *Case management overview at Enforcement Team Meeting.*

7/03 *Case management overview at Enforcement Team Meeting.*

19. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).

7/02 *Discussed Citation and Fine Program at July board meeting. Board approved board member and supervising inspector to hear office conference appeals.*

8/02 *Held 2 Citation and Fine meetings.*

9/02 *Held 1 Citation and Fine meeting.*

9/02 *Since program inception, reviewed 143 cases and issued 309 citations.*

9/02 *Discussed Citation and Fine Program and changes to internal operations.*

9/02 *Reviewed 154 quarterly probation reports, met with 28 new probationers and completed 101 probation inspections.*

10/02 *Advised board of proposed legislative changes to enhance board's enforcement tools to be discussed at December committee meeting.*

10/02 *Held 1 Cite and Fine meeting.*

12/02 *Discussed proposed legislative changes to enhance board's enforcement tools to seek compliance with pharmacy law.*

12/02 *Discussed Citation and Fine Program as requested by the Joint Legislative Sunset Review Committee (JLSRC) to consider delegation to the executive officer. Made recommendation to the board.*

12/02 *Completed 133 probation inspections.*

12/02 *Held 3 Cite and Fine meetings.*

12/02 *Since program inception, reviewed 195 cases and issued 616 citations.*

1/03 *Board adopted JLSRC's recommendation to delegate cite and fine authority to executive officer.*

1/03 *Held 2 Cite and Fine meetings.*

2/03 *Held 1 Cite and Fine meeting.*

3/03 *Held 2 Cite and Fine meetings.*

3/03 *Regulation change to Cite and Fine program was noticed.*

4/03 *Held 1 Cite and Fine meeting.*

4/03 *Citation data reported at April board meeting.*

5/03 *Held Cite and Fine meetings.*

6/03 *Held 2 Cite and Fine Meetings.*

7/03 *From 3/03 – 6/03, held 20 probation conferences and held 3 PRC meetings.*

7/03 *Completed 582 probation inspections for 2002/03.*

7/03 *Hired new contractor Maximus to administer the PRP.*

7/03 *Reported citation data at July Board Meeting.*

20. Pursue criminal convictions of the most egregious violations, using specialized investigators in the department's Division of Investigation.

21. Identify and remove impediments to efficient enforcement.

9/02 *Held public Enforcement Committee and Team meetings to discuss quality improvement efforts (case management), the citation and fine process, DCA and BOP complaint disclosure policy, quality assurance program, enforcement guidelines for unprofessional conduct, proposed changes to the wholesaler program, and board-sponsored CE program on pharmacy law.*

12/02 *Held public Enforcement and Team meetings to discuss quality improvement efforts (case management), citation and fine process, quality assurance program, requirement that board inspectors be pharmacists, proposed changes to wholesaler program, CE for pharmacists who attend board meetings and implementation of HIPPA.*

3/03 *Held public Enforcement and Team meetings to discuss quality improvement efforts (case management), changes to pharmacy practice, proposed modifications to quality assurance regulations and HIPAA implementation.*

7/03 *Held public Enforcement and Team meetings to discuss quality improvement efforts (case management), prescription drugs from Canada, proposed modifications to quality assurance regulation, regulation regarding wholesaler delivery to pharmacies after hours, request for prescription records by authorized officers of law, off site order entry of hospital medication orders, joint task force on prescriber dispensing and implementation of HIPAA.*

22. Improve public service of the Consumer Inquiry and Complaint Unit.

8/02 *Suspended consumer satisfaction survey because of program changes – will reinstate in November.*

9/02 *Revised consumer complaint handling process. Updated letters and notification to consumers.*

10/02 *Implemented program changes.*

1/03 *Implemented telephone survey on consumer satisfaction.*

4/03 *Department recommends that board review its survey instrument and not to perform telephone survey.*

4/03 *Implemented an on-line consumer complaint form on the board's Web site.*

7/03 *Reported consumer satisfaction survey data. Discussed methods to improve response rate and feedback.*

23. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

9/02 *Revised notification form for possible violations.*

12/02 *Added and centralized new form macros for consumer complaint process.*

12/02 *Automated inspection-tracking program to include status 3 inspections.*

3/03 *Automated case-tracking program for administrative cases.*

4/03 *Initiated revisions to inspector activity tracker.*

4/03 *Added on-line consumer complaint form to website.*

24. Cooperate with other federal, state and local law enforcement agencies to pursue effective enforcement of pharmacy law.

9/02 *Attended two FBI diversion meetings.*

11/02 *Assisted the State Food and Drug and FBI.*

11/02 *Conducted investigation with DEA.*

12/02 *Participated on BNE task force meetings and investigations.*

3/03 *Participated on BNE task force meeting.*

4/03 *Attended Task Force meeting with FBI, HHS, Medi-Cal Fraud, and FDA.*

5/03 *Worked with (DEA/BNE) local law enforcement on Task Force related to major oxycotin investigation.*

5/03 *Worked with Medi-Cal on major fraud case.*

5/03 *Attended Task Force meeting with FBI, HHS, Medi-Cal Fraud, and FDA.*

6/03 *Attended Task Force meeting with FBI, HHS, Medi-Cal Fraud, and FDA.*

25. Respond to specialized information requests from other boards and agencies about board programs, licensees (e.g., subpoenas) and Public Records Act requests.

9/02 *Recommended changes to the board's Complaint Disclosure Policy.*

10/02 *Board adopted new Complaint Disclosure Polity.*

7/03 *For 2002/03 responded to 1,390 public requests and 11 subpoenas.*